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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,783	12/21/2000	Kenneth Jacobs	GIN-6054CP	1408

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EXAMINER
MITRA, RITA

ART UNIT	PAPER NUMBER
1653	8

DATE MAILED: 07/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/746,783	JACOBS ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Preliminary amendment filed on 12/21/00* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30,31,68,69,108,109,114,121,165,166,192,198,238,239,253 and 260* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/21/00* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continuation of Disposition of Claims: Claims withdrawn from consideration are 31,68,69,108,109,114,121,165,166,192,198,238,239,253 and 260.

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 30, drawn to an isolated polynucleotide comprising or related to SEQ ID NO: 18, classified in class 536, subclass 23.1.

II. Claim 31, drawn to an isolated protein comprising or related to SEQ ID NO: 19, classified in class 530, subclass 350.

III. Claim 68, drawn to an isolated polynucleotide comprising or related to SEQ ID NO: 49, classified in class 536, subclass 23.1.

IV. Claim 69, drawn to an isolated protein comprising or related to SEQ ID NO: 50, classified in class 530, subclass 350.

V. Claim 108, drawn to an isolated polynucleotide comprising or related to SEQ ID NO: 83, classified in class 536, subclass 23.1.

VI. Claim 109, drawn to an isolated protein comprising or related to SEQ ID NO: 84, classified in class 530, subclass 350.

VII. Claim 114, drawn to a composition comprising an isolated polynucleotide comprising or related to SEQ ID NO: 97, classified in class 536, subclass 23.1; class 514, subclass 2.

VIII. Claim 121, drawn to a composition comprising an isolated protein comprising or related to SEQ ID NO: 98, classified in class 530, subclass 350; class 514, subclass 2.

IX. Claim 165, drawn to an isolated polynucleotide comprising or related to SEQ ID NO: 131, classified in class 536, subclass 23.1.

X. Claim 166, drawn to an isolated protein comprising or related to SEQ ID NO: 132, classified in class 530, subclass 350.

XI. Claim 192, drawn to an isolated polynucleotide comprising or related to SEQ ID NO: 159, classified in class 536, subclass 23.1.

XII. Claim 198, drawn to an isolated protein comprising or related to SEQ ID NO: 160, classified in class 530, subclass 350.

XIII. Claim 238, drawn to an isolated polynucleotide comprising or related to SEQ ID NO: 187, classified in class 536, subclass 23.1.

XIV. Claim 239, drawn to an isolated protein comprising or related to SEQ ID NO: 188, classified in class 530, subclass 350.

XV. Claim 253, drawn to an isolated polynucleotide comprising or related to SEQ ID NO: 207, classified in class 536, subclass 23.1.

XVI. Claim 260, drawn to an isolated protein comprising or related to SEQ ID NO: 208, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

The DNA of groups I, III, V, VII, IX, XI, XIII, and XV are unrelated. They differ with respect to their structures and physicochemical properties. The polynucleotides have separate and distinct sequences and encode unrelated proteins. Therefore, the inventions are distinct.

The proteins of groups II, IV, VI, VIII, X, XII, XIV and XVI are unrelated. The polypeptides have separate and distinct sequences encoding unrelated proteins. Therefore, the inventions are distinct.

The DNA of groups I, III, V, VII, IX, XI, XIII, and XV is related to the protein of groups II, IV, VI, VIII, X, XII, XIV and XVI by virtue of the fact that the DNA codes for the protein, respectively. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays. Therefore, the inventions are distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

During a telephone conversation with Attorney Lawrence Perry on June 6, 2002 a provisional election was made without traverse to prosecute the invention of Group I, claim 30. Affirmation of this election must be made by applicant in replying to this Office action. Claims 31, 68, 69, 108, 109, 114, 121, 165, 166, 192, 198, 238, 239, 253 and 260 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Therefore, claim 30 is currently pending and is under examination.

Priority

It is noted that applicant has cited one or more applications as priority documents under 35 U.S.C. 119(e) and 120. Applicant is requested to update the status of the documents to reflect their current status. The provisional applications have not provided any CRF. All parent applications except 09/092722 fail to provide the support to clone fq505_4 and SEQ ID NO: 18 and SEQ ID NO: 19. Therefore, Application 09/092722 filed on June 5, 1998 is considered for the priority date applied in the present application.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title"

Claim 30 is rejected under 35 U.S.C. 101 because the specification does not provide either a specific or substantial asserted utility or a well-established utility, and thus, does not support the claimed invention. The claimed polynucleotides are not supported by either a specific asserted utility or a well established utility because the specification fails to assert any utility for the claimed polynucleotides or the encoded proteins and neither the specification as filed nor any art of record disclose or suggest any activity for the claimed polynucleotides or the encoded proteins such that another non-asserted utility would be well established. Note, because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility cannot be assessed.

The specification, on pages 14-16 and 144-145 describes clone fq505_4 to which the instant invention relates. Applicants assert (page 145) that based on various alignments with database submissions; the claimed polynucleotides may encode polypeptides that share some activity with P92141 (Recombinant human adult T cell leukemia derived factor polypeptide), X54539 (thioredoxin), X77584 (ATL-derived factor/thioredoxin), GenProt135773 (surface associated sulphydryl protein) for example. The alignments have not been provided and no percent similarity is disclosed. The specification fails to provide any activity of the polynucleotide sequence of the clone fq505_4 or any activity of the protein encoded by the claimed polynucleotide, which would be similar as to the activity of an ATL-derived factor protein or a thioredoxin protein or a sulphydryl protein.

A sequence comparison search for SEQ ID NO: 18 and SEQ ID NO: 19 using FastDB sequence database indicates the alignments and percent similarity to sequences cited by the applicants and indicated having similar activity (specification page 145), identified as Accession NOs:

X77584 teach a nucleic acid sequence having 38% sequence identity to SEQ ID NO: 18 (see comparison result, FastDB, IntelliGenetics database).

X54539 teach a nucleic acid sequence having 31% sequence identity to SEQ ID NO: 18 (see comparison result, FastDB, IntelliGenetics database).

A sequence identity search for SEQ ID NO: 18 and SEQ ID NO: 19 using nucleic acids and protein sequence databases indicates a secreted protein having 100% nucleic acid sequence identity to SEQ ID NO: 18, (see alignment result, Database: N_Geneseq_032802, Accession NO: AAV99731) and 100% amino acid sequence identity to SEQ ID NO: 19, (see alignment result, Database: A_Geneseq_032802, Accession NO: AAW95351). Thus it indicates that the SEQ ID NO: 18 and SEQ ID NO: 19 has a higher sequence identity to secreted protein (discussed in 102 rejection, this office action) compared to sequence identity to thioredoxin as in X54539 or ATL-derived factor protein as in X77584 (see specification page 145). Therefore, only on the basis of some similarity to sequences identified as thioredoxin or ATL-derived protein, the protein of clone fq505_4 cannot be identified as a member of 'thioredoxin' or "ATL-derived" protein family. Moreover, the specification fails to provide any activity of the polypeptide of SEQ ID NO: 19, which would be similar to the activity of a 'thioredoxin' or "ATL-derived" protein.

Based on the specification (pages 14-16 and 144-145), no biological activity has been set forth for the polypeptide encoded by polynucleotide of clone fq505_4 nor any use for the polynucleotide itself has been provided. However, speculative biological activities have been provided on pages 210-226 of the specification. For example, the use of the polynucleotide for further research is described here (page 210). This use is not an acceptable patentable utility because one skilled in the art should not have to discover for themselves the use of the claimed polynucleotides. This situation requires carrying out future research to identify or reasonably confirm a "real world" context of use and therefore do not define specific and substantial utility.

The specification on page 211 states that the polynucleotide and proteins can be used as a nutritional source or supplements. This use is considered to be a " throw away" utility and does not distinguish the claimed polynucleotide over any other polunucleotide. The utility is not specific or substantial.

Other activities that the protein encoded by the polynucleotide may exhibit are listed throughout pages 210-226 of the specification. However, these activities are purely speculative. In summary, the polynucleotides claimed do not have a credible, specific or well-established utility and therefore lacks utility under 35 U.S.C. 101.

Claim 30 (i), is drawn to a polynucleotide encoding a protein comprising a fragment of SEQ ID 19. The specification does not describe the functional properties of these protein fragments, and the structural information is limited. While the specification enumerates several known assays for biological activity (pp. 210-226), it does not guide the selection of a specific assay that would be used to screen the biological activities of the claimed fragments.

Claim 30 (d, e) is directed to polynucleotides encoding full-length proteins of clone fq505_4. It is not clear from the description of the clone (specification page 14-16, 144-145) about the protein structure, aside from its full-length amino acid sequence, and/or its function.

Claim 30 (a-c, l) are directed to polynucleotides comprising the sequence of SEQ ID NO: 18 and fragments thereof. As discussed above, based on the specification (pages 14-16, 144-145) it is unclear what activity the claimed polynucleotides possess, what activity the encoded proteins possess and therefore unclear how a person having skill in the art might use the claimed polynucleotides. It would require undue experimentation for a person having skill in the art to be able to use the claimed polynucleotides. It is *a priori* unpredictable based on the instant disclosure what activity the claimed polynucleotides possess because no correlation has been made between the claimed polynucleotides and a specific activity.

In the instant case, the failure of applicants to specifically identify why the claimed invention is believed to be useful renders the claimed invention deficient under 35 USC 101. No specific biological activity has been identified for the protein set forth in SEQ ID NO: 19 or for the polynucleotides of SEQ ID NO: 18 encoding the protein other than the fact that the protein may be secreted (p. 145). The person having ordinary skill in the art would not be able to identify any specific activity for the protein comprising or related to SEQ ID NO: 19 based on its structure alone for the reasons set forth above. General statements that a composition has an unspecified biological activity or that do not explain why a composition with that activity is believed to be useful fails to set forth a "specific utility." Brenner v. Manson, 383 US 519, 148 USPQ 689 (Sup. Ct.1966) (general assertion of similarities to known compounds known to be useful without sufficient corresponding explanation why claimed compounds are believed to be similarly useful is insufficient under 35 USC 101).

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial or well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 30 is rejected because it recites necessity of a deposited clone, ATCC 98451, and does not meet fully with the deposit requirements. The specification at page 197 indicates that the deposit has been made under the Budapest Treaty, and the composite deposit of several clones (including clone fq505_4) has been deposited with ATCC and were given the Accession number ATCC 98451. However, Applicants fail to provide a copy of the deposit receipt. Submission of a copy of the receipt would overcome this rejection.

Furthermore, the claim 30 embrace species homologues and allelic variants.

Claim 30(k) is drawn to a polynucleotide, which encodes a species homologue of the protein of (h) or (i) of claim 30. There is no guidance about what percent identity the two encoding genes must have, no specific probe/primer and specific hybridization of PCR conditions, which can be used so that one would reasonably expect the DNA obtained under those specific conditions is a species homologue. The specification provides insufficient guidance to allow one skilled in the art to obtain species homologues because the method to do so presented on page 205, lines 10-14, 21-23 recites only ..."making suitable probes or primers from the sequences provided herein and screening a suitable nucleic acid source from the desired species." There is no information about how to identify a "suitable" probe or primer.

Additionally, species homologues often display low sequence identity so that identification based solely on sequence similarity is unpredictable. Under such common circumstances, if one cannot test for an expected activity of the encoded putative species homologue, then it is impossible to confirm existence of species homologues. Neither sufficient structural guideline to reliable identify species homologues nor a specific function which could be used to confirm that an isolated nucleic acid was a species homologue of a recited polypeptide is provided in the specification. Further, the term "homologue", if only sequence similarity is used to establish "homology", cannot define a connection of common evolutionary origin. Nucleic acids, which encode proteins that are species homologue, would have a common evolutionary origin. For these reasons, it would require undue experimentation to determine if the compound has biological activity and, therefore, to make and use the claimed invention.

Claim 30(j) directs to an allelic variant of a polynucleotide of (a-g) of claim 30. The specification describes allelic variations as "naturally-occurring alternative forms of the isolated polynucleotide which also encode proteins which are identical, or have significantly similar sequences to those encoded by the disclosed polynucleotides (description page 206, lines 1-4). According to Ayala et al. (Modern Genetics, Glossary), an allele is "one of two or more alternative forms of a gene, each possessing a unique nucleotide sequence; different alleles of a given gene are usually recognized, however, by the phenotypes rather than by comparison of their nucleotide sequences." The current description has disclosed no genes, where gene means genomic DNA, comprising the coding sequence of a protein. The sequences, which are disclosed, are those of cDNA. If two cDNAs differ from each other, it is impossible to tell, without the genomic DNA in hand, whether the difference arose because of an allelic variation, transcriptional modification going from genomic DNA to mRNA, post transcriptional processing of RNA, or an error in reverse transcription of mRNA into cDNA. The nature of allelic variation makes it entirely unpredictable what might be considered an allele before the isolation of such a sequence has actually taken place. The specification does not describe what might be considered an allele of the DNA of section (a-j) of claim 30 or provide any examples of the same. Since the disclosed cDNA encoding a polypeptide has not been ascribed a specific function, it does not appear that allelic variants have been isolated or identified. There are no examples of allelic

sequences of the claimed DNA to which one could compare undisclosed DNA to determine if they are also alleles. For these reasons the claimed allelic variants have not been adequately described, and a person having ordinary skill in art would not recognize a specific utility for the polynucleotide and would not know how to use them.

Also, if you don't know what an allelic variant or homologue looks like, what then does a hybridized polynucleotide look like. Therefore, polynucleotides that hybridize to the allelic variants or homologues that are not described cannot be envisioned by the teachings of the specification.

Claim 30 (l) is directed to a polynucleotide sequence that hybridizes to the polynucleotides of section (a-i) of claim 30. Applicants have not sufficiently defined the specific conditions of stringency under which the hybridization is to take place. Although several stringent conditions: highly stringent, stringent and reduced stringent conditions are listed in the table given on the page 206 of the specification.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

"The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

Claims 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30 is indefinite because it is not clear from the claim or the specification how in claim 30 (l), that the polynucleotide that must hybridize to the polynucleotide of items (a-i) of claim 30 encodes the same protein. In one instance, the polynucleotide is the coding strand and in the other it is the non-coding strand. If the coding strand contains 5' ATG (encodes Met), the non-coding strand is 5' CAT (encodes His). Claim 30 (l) also refers to "stringent conditions," however; both the specification and the art lack an unambiguous definition of that term. The specification (page7-9) describes highly stringent, stringent and reduced stringent conditions, however without defining stringent conditions the claim remains indefinite on the basis of

absence of definition of "stringent conditions". This rejection can be overcome by including in the claim the specific stringent conditions.

Claims 30(i) is indefinite since it is unclear by the absence in the claim recitation whether or not the polynucleotide encodes a polypeptide fragment that is active, or what that activity may be. The use of term "biological activity" renders the claim indefinite because it is not clear what that specific biological activity is.

Note that "ATCC" is a registered trademark. Please spell out in full as "American Type Culture Collection"and delete "ATCC" from the claim.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 30 is rejected under 35 USC 102 (a) as being anticipated by Agostino et al. (June 11, 1997). Agostino et al. (AAV99731) teach a cDNA clone fq505_4 codes for a human secreted protein (AAW95351) from human adult testis cDNA library, wherein the secreted protein nucleic acid sequences correspond to clone fq505_4 having 100% nucleic acid sequence identity to SEQ ID NO: 18, (see alignment result, Database: N_Geneseq_032802, Accession NO: AAV99731) and 100% amino acid sequence identity to SEQ ID NO: 19, (see alignment result, Database: A_Geneseq_032802, Accession NO: AAW95351). Agostino's cDNA insert length is 481 bp, that encodes a protein having 107 amino acids of SEQ ID NO: 19, therefore this sequence is considered for hybridizing to the polynucleotide of claim 30 that encodes a protein of SEQ ID NO: 19. Agostino's clone fq505_4 is deposited in composite clone ATCC 98451, thus Agostino et al. anticipate claims 30 of the instant application.

Claim 30 is rejected under 35 USC 102 (a) as being anticipated by Jacobs et al. (WO 98/56909, June 11, 1997). Jacobs et al. ('909) teach a polynucleotide as set forth in SEQ ID NO: 1 encoding human secreted protein as set forth in SEQ ID NO: 2 (claim 1 of '909). The cDNA clone fq505_4 of Jacob is deposited in composite clone ATCC 98451 (see summary and claim 1 and page 16, 29 and 32, of '909), thus anticipating claim 30 of instant application. Jacobs' polynucleotide sequence is considered for hybridizing to the polynucleotide of SEQ ID NO: 18 of claim 1 (a-i); and polypeptide sequence is considered for a protein of SEQ ID NO: 19; and thus anticipates claim 30 of instant application.

Conclusions

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 p.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Rita Mitra, Ph.D.
June 24, 2002